



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/457,771	12/09/99	EMANUELE	R 19720-0624

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HM12/0726

EXAMINER

SCHNIZER, R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/26/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Advisory Action**Application No.  
**09/457,771**Applicant(s)  
**Emanuelle et al**Examiner  
**Richard Schnizer**Group Art Unit  
**1632**

THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☐ expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

**Applicant's response to the final rejection, filed on Jun 27, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

- ☒ The proposed amendment(s):
- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
  - ☒ will not be entered because:
    - ☒ they raise new issues that would require further consideration and/or search. (See note below).
    - ☐ they raise the issue of new matter. (See note below).
    - ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
    - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

See attached

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: \_\_\_\_\_

Claims objected to: \_\_\_\_\_

Claims rejected: 1-16

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.

- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

- ☒ Other See attached

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### **ADVISORY ACTION**

This case is a Continued Prosecution Application. An amendment was received on 6/27/00, but was not entered. Applicant has indicated that the amendment is responsive to the final rejection in the parent case (09/104,088) mailed 9/10/99. However, the amendment was mailed two weeks after the first action in the current case. Because the first action was properly made final, this amendment is considered an after-final amendment. The amendment was not entered because it introduces new grounds of rejection, and because it does not place the application in better form for appeal. Specifically, claims 1-8 have been amended to include the phrase "approximately less than 50%". This phrase is indefinite because it is unclear what is the upper end of the acceptable range.

### ***Response to Arguments***

#### ***Enablement***

Applicant argues that the claimed compositions and methods are enabled for therapeutic purposes because the compositions and methods have been used to successfully deliver nucleic acid in vivo, resulting in a protective immune response to the encoded antigen. See example XIII on page 30.

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This argument is not convincing because the significance of the data in Example XIII is unknown. The number of animals in the study is not reported, it is unknown how much plasmid DNA was injected into the control and experimental animals, and it is unclear how long the experimental animals survived. For example, if survival was increased by only one or two days, then these results would be insignificant. As stated in the previous actions, the art of gene therapy is extremely unpredictable. Because Applicant has failed to provide clearly significant experimental results in support of claims directed to nucleic acid therapy, the rejection is maintained.

### ***Obviousness***

Applicant's argument that the cited art does not teach the limitations of the claims is unpersuasive because Allison teaches both POP and POE molecular weights in the range of the claimed invention. Allison, Hunter and Stephens in combination teach all of the limitations of the claims, and Applicant does not assert that the references are not combinable.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached on Mondays and Thursdays between the hours of 6:20 AM

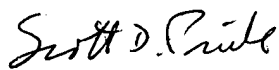
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and 3:50 PM, and on Tuesdays, Wednesdays and Fridays between the hours of 7:00 AM and 4:30 PM (Eastern time). The examiner is off every other Friday, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached at 703-308-2801. The FAX phone numbers for art unit 1632 are 703-308-4242 and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Richard Schnizer, Ph. D.

  
**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**